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September 21, 1999
Date


Shelley P.M. Fussey



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Philip E. Thorpe and Sophia Ran

Serial No.: 09/351,149

Filed: July 12, 1999

For: CANCER TREATMENT KITS
COMPRISING THERAPEUTIC
CONJUGATES THAT BIND TO
AMINOPHOSPHOLIPIDS

Group Art Unit: 1623

Examiner: Unknown

Atty. Dkt. No.: 4001.002383

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.98 (a)(3), a concise explanation of the relevance of the two foreign language articles submitted, as they are presently understood, is supplied below. The statements submitted herewith are taken from the abstracts issued by Derwents World Patent Index, as presented in file 351 on the Dialog Information System. Applicants' submission of a translation of the abstracts alone is motivated solely by the high cost of obtaining a translation of the full length documents, and should in no way be interpreted as a failure to comply with the duty of disclosure or an intent to deceive the Examiner.

Patent No. WO 91/07187

"The anticoagulant is selected from annexine and its natural, synthetic or genetically prepd. deriv. or analogues. It is administered with adjuvants, carriers and/or stabilizers. Pharmaceuticals are claimed which contain a particular annexine, whose formula is given in the specification. This compound is 320 amino acid residues long, contains a Glu or a Sp residue in the 22 position and opt. a disulphide bridge between the 316-Cys and the 2-Ala. The 2-ala can also be blocked, and the 1 Met group may be absent. Admin. Is intravenous, intramuscular or subcutaneous and the daily dose is 0.005-0.5 (0.01-0.05) mg/kg. The annexines may also be administered topically.

USE/ADVANTAGE - The composition inhibits the procoagulant activity of tumor cells, and hence their encapsulation in a fibrin net."

Patent No. WO 97/17084

"Modulation of phosphatidylserine (PS)-dependent phagocytosis (engulfment phagocytosis) comprises changing the level and/or distribution of annexin and/or modifying the active site and/or partner.

USE - Annexin V (Ia) is admin. to modulate the immune response, partic. in tumor therapy, tumor vaccines, treatment of viral infections (specifically HIV), treatment of sickle cell anemia and malaria (or malaria immunization). Blocking PS-dependent phagocytosis can also prevent cell loss during storage of blood prods. used *e.g.*, to treat sick cell anemia (all claimed). (I) are admin. by injection or it is expressed as a fusion protein with a leader sequence, using a transient RNA vector system in blood cells.

ADVANTAGE - Blocking PS-dependent phagocytosis means that PS-carrying cells undergo phagocytosis by other pathways, leading to a far greater immune response, *i.e.* the treatment provides an adjuvant effect to increase immunogenicity of tumor vaccines, etc. In viral infections, apoptotic material taken into phagocytes causes a respiratory burst that destroys the viral genome."

Applicants also take the opportunity to disclose that Dr. Sophia Ran, one of the listed inventors, presented information concerning "Targeting Coagulants to Tumor Vasculature" at a confidential Gordon Research Conference on Drug Carriers in Medicine and Biology, held February 22-27, 1998 (see attached summary). As an Examiner of a biotech application likely knows, Gordon Research Conferences are confidential, are not associated with written publications, are not associated with the dissemination of information outside the conference,

and the information discussed therein is not reproduced in any form or even indexed in any library or database.

Also, in the present instance, it is clear that Dr. Ran presented information concerning targeting coagulants to tumor vasculature less than a year before the priority date of the present application, *i.e.*, February 22-27, 1998 *vs.* July 13, 1998. From the title of the information presented, and the recollection of those concerned, it also appears that the information was likely to be only of background relevance to the presently claimed invention.

Nonetheless, and *solely* as a precaution to be seen to completely comply with the duty of disclosure under Rule 56, Applicants elect to disclose that Dr. Ran gave a presentation concerning targeting coagulants to tumor vasculature at a confidential Gordon Conference during February 1998.

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Assistant Commissioner is hereby authorized to deduct said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/4001.002383.

Applicant respectfully requests that the listed documents and information be made of record and considered in the present case.

Respectfully submitted,



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Agent for Applicants

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Date: September 21, 1999